Prometheus Laboratories

Please fill in, sign and fax to 877-816-4019 **Date: ____/____/____**

Informed Consent Compliance – Hospital/Laboratory/Physician for Genetic Testing*

Name of Hospital / Laboratory / Physician_____("Client")

Hospital / Laboratory / Physician Phone Number_____

Address_____

City, State & Zip_____

*When Prometheus Laboratories Inc. receives genetic test orders for Celiac Genetics, Celiac PLUS, TPMT Genetics, Respondr® TNF or RiskImmune® from its hospital, laboratory and/or physician clients, Prometheus requires assurance that Clients have a process in place to comply with applicable informed consent requirements related to such testing.

For all genetic testing submitted to Prometheus by Client, I certify that Client has an appropriate process in place to comply with informed consent requirements under applicable state laws and/or regulations that require medical professionals who order genetic testing to obtain the informed consent of the patient for such testing.

This attestation remains in effect until an updated form is submitted.

Signature of Hospital Official / Laboratory Official / Physician_____

Print Name_____

Signatory Title_____

Background
Some state laws require that individuals (or their authorized representative) provide written informed consent (some states permit oral informed consent) to the physician ordering genetic testing and/or releasing test results. Where applicable, the individual (or authorized person) must sign and date a consent form, or otherwise provide informed consent that includes a statement:

I warrant that this test was ordered and that I have obtained the appropriate prior written consent. This written consent was signed by the person who is the subject of the test (or if that person lacks capacity to consent, signed by the person authorized to consent for that person) and includes the following (unless certain that the following information is not required by the state in which I practice):

1. The purpose of this test is to determine if the patient may have a variant in the gene(s) being tested, which has been found to be associated with this condition.
2. This test will only test for this specific condition and will not detect ALL possible variants within this gene, nor will it detect variants in other genes.
3. Prior to my signature of the written consent, a qualified healthcare professional discussed with the patient the genetic test ordered and described the steps involved in the test, the constraints of the procedure, and its accuracy.
4. My patient was advised by a qualified healthcare professional of the risks and benefits of genetic testing, and advised of the significance of a positive and negative result.
5. The patient understands that a positive test result is an indication that the patient may be predisposed to, or have, the condition listed.
6. The patient understands that the test may fail, that the results may be non-informative or not predictive for his/her case, and that the test may reveal information that is unrelated to their intended purpose.
7. No unauthorized test is performed on specimens.
8. NY-state specimens will be destroyed within 60 days after collection when no longer required for clinical purposes.
9. The informed consent does not authorize the use or release of any other identified medical information unrelated to this genetic test.
10. The patient understood that he/she could see professional genetic counseling prior to undergoing the testing procedure, and received written information identifying a genetic counselor or medical geneticist by his/her treating provider.